FEB 2 4 2010

K 100228

Attachment 6 - 510(k) Summary of Safety and Effectiveness - VersaPulse P20 Laser System

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This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

6.1. SUBMITTER INFORMATION:

Submitter's Name:	Lumenis, Inc.
Address:	3959 West 1820 South Salt Lake City, UT 84104
Contact:	Douglas Stante
Phone:	801-656-2620
Fax:	801-565-2627
Date of Preparation:	January 20, 2010

6.2. DEVICE NAME:

Trade Name(s):	VersaPulse P20 Laser System
Common/Usual Name:	powered laser surgical instrument
Classification Names:	79 GEX
CFR Reference:	21 CFR 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology

6.3. PREDICATE DEVICE:

The predicate device is the Holmium 20 Watt VersaPulse PowerSuite (Ho:Yag) and Dual Wavelength (Ho: Yag/ Nd:Yag) Surgical Lasers, K011703, August 29, 2001.

6.4. DEVICE DESCRIPTION:

The VersaPulse P20 Laser System is a desktop 20 Watt surgical Holmium laser and is an improved model configuration of the 20 Watt VersaPulse PowerSuite Holmium Surgical Laser, [510 (k) K011703].

Main functional components :

- A Laser console
- Control and display panel
- A fiber port for Laser delivery systems
- A covered foot switch
- Operating software
- A variety of fiber optic delivery devices with accessories

The system uses the same type of laser delivery devices as the predicate.

6.5. INTENDED USE:

The VersaPulse P20 Laser System is intended for use in surgical procedures requiring open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue.

6.6. TECHNOLOGICAL CHARACTERISTICS SUMMARY & SUBSTANTIAL EQUIVALENCE STATEMENT:

The subject device, the VersaPulse P20 Laser System, has the same intended use, general design and same fundamental scientific technology as the Lumenis predicate device.

6.7. PERFORMANCE DATA SUMMARY:

The appropriate testing, including safety, performance and functional testing, to determine substantial equivalence of the VersaPulse P20 Laser System has been conducted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

FEB 2 4 2010

Lumenis, Inc.
% Mr. Douglas Stante
Global Director Regulatory and
Quality Systems Compliance
3959 West 1820 South
Salt Lake City, Utah 84104

Re: K100228
Trade/Device Name: VersaPulse P20 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 25, 2010
Received: February 01, 2010

Dear Mr. Stante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2 - Indications for Use Statement

510(k) Number (if known) K 100228

Device Name *VersaPulse P20*

Indications for Use

The VersaPulse P20 Ho:YAG (2.1 μm wavelength) is indicated for use in surgical procedures involving open, laparoscopic and endoscopic ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

- Arthroscopy
- Urinary lithotripsy
- Gynecological surgery
- Gastroenterological surgery
- Urology
- ENT surgery
- General surgery

Prescription Use_____X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100228